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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,209	12/18/2000	Jaan Noolandi	A0489-US-NP	4337
PARC-XEROX/BSTZ BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP 1279 Oakmead Parkway Sunnyvale, CA 94085-4040			EXAMINER	
			BLIZZARD, CHRISTOPHER JAMES	
			ART UNIT	PAPER NUMBER
			3771	
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			04/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	09/740,209	NOOLANDI ET AL.			
Office Action Summary	Examiner	Art Unit			
	CHRISTOPHER BLIZZARD	3771			
The MAILING DATE of this communication ap Period for Reply	ppears on the cover sheet with th	ne correspondence address			
• •	LV IO OET TO EVEIDE AMONE	FLVO) OD TUUDTV (OO) DAVO			
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING I - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perior Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICAT 1.136(a). In no event, however, may a reply but d will apply and will expire SIX (6) MONTHS to the cause the application to become ABANDO	ION. be timely filed from the mailing date of this communication. DNED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on <u>05</u>	March 2010.				
	<u> </u>				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>1-7,9-17,19 and 21-26</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-7,9-17,19 and 21-26</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
9)⊠ The specification is objected to by the Examiner.					
10)⊠ The drawing(s) filed on <u>18 June 2009</u> is/are: a)⊡ accepted or b)⊠ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the E	=xaminer. Note the attached Oπ	lice Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:					
1.☐ Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summ				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Ma 5) Notice of Inform 6) Other:	al Patent Application			

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/5/10 has been entered.
- 2. As directed in amendment filed 3/5/10 claims 1, 9, 11, 12, 14, 23 and 26 were amended, claims 8, 18, and 20 were cancelled, and not claims were added. Therefore this application currently has claims 1-7, 9-17, 19 and 21-26 pending.

Drawings

- 3. The amendment to figure 4 filed on 6/18/09 is acknowledge. However, the addition of the UV source (430) does not show the structural relationship with the device, and thus renders the drawings not acceptable.
- 4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "Fresnel lens", "multiplexing circuit" and "ultraviolet radiation source" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The amendment filed 3/5/10 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The drive circuit including a multiplexing circuit.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of "a plurality of lenses positioned between at least one transducer and the capillary wave" is not described in the specification. Specifically the circumstances describing how a plurality of lens are located between a single transducer and a single capillary wave.

- 8. Claims 15-17 and 22 are rejected under 35 U.S.C. 112, first paragraph due to there dependency on claim 14.
- 9. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 10. Claims 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 11. Regarding claim13, the phrase "MEMS cover" renders the claim indefinite because it is unclear what is being claimed.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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13. Claim 1, 2, 4, 5, 19, 23 and 26 are rejected under 35 U.S.C. 102(b) as being

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anticipated by Hauser (5,485,828).

14. Regarding claims 1 and 26, Hauser discloses an apparatus for delivering a pharmaceutical product comprising: a first driver element (16) to generate acoustic energy, the first driver generating acoustic energy in pulses that are of a short duration and low frequency (column 2, lines 50-52) such that a droplet pharmaceutical product is output from a capillary wave (26) (column 1, lines 30-35; column 2, lines 58-60); a first acoustic lens (34) positioned between the first driver element and the capillary wave (fig. 1) to focus the acoustic energy generated by the first driver element; and a delivery system to maintain the pharmaceutical product in a position to receive the acoustic energy from the first acoustic lens and cause ejection of the droplet of pharmaceutical product (fig. 1, within 24).

- 15. Regarding claim 2, Hauser discloses a source of electrical power (20) coupled to the first driver element (16).
- 16. Regarding claim 4, Hauser discloses the first acoustic lens (34) being made of plastic (column 3, lines 37-42).
- 17. Regarding claim 5, Hauser discloses a second acoustic lens to focus energy generated by the first driver element and cause ejection of a second droplet of pharmaceutical product (column 3, lines 25-30).
- 18. Regarding claim 19, Hauser discloses the delivery system includes a section (32) for insertion into a human orifice (column 2, lines 62-63).

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19. Regarding claim 23, Hauser discloses the claimed method in the device disclosed above.

Claim Rejections - 35 USC § 103

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- 20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 21. Claims 3, 6, 13, 9-11, 14-16, and 22 as best understood are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser (5,485,828).
- 22. Regarding claim 3, Hauser teaches the use of fresnel lens as acoustic lens (column 1, lines 57-59), there it would have been obvious to one of ordinary skill in the art at the time of the invention to use a fresnel lens for an acoustic lends, since it would perform equally well.
- 23. Regarding claim 6, Hauser discloses a portable energy source (20) (column 2, lines 22-24) connected to a first driver element (16) but does not disclose it connected to a second driver element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the portable energy source attached to a second driver element, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.
- 24. Regarding claims 9 and 11, Hauser discloses the claimed invention above wherein various frequencies can be used (column 3, lines 30-33) but does not disclose

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the frequency being below 15 MHz. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a frequency below 15 Mhz, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

- 25. Regarding claim 10, Hauser discloses the droplets of pharmaceutical product being less than 10 micrometers in diameter (column 4, lines 7-9).
- 26. Regarding claim 13, Hauser discloses the driver element being covered by multiple components that could be considered to be covers when the driver element is not outputting acoustic energy but does not disclose the covers to be MEMS cover. It would have been obvious to one of ordinary skill in the art at the time of the invention to construct the cover as a MEMS cover, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a protection to the driver element. In re Dailey and Eilers, 149 USPQ 47 (1966).
- 27. Regarding claims 14-16 and 22, Hauser discloses the claimed invention above where a plurality of lenses are located being a transducer and the resulting capillary waves (column 3, lines 25-30).
- 28. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser (5,485,828) as applied in claim 6 above and further in view of Sweet (5,832,428).
- 29. Regarding claim 7, Hauser does not disclose a multiplexing circuit. Sweet discloses an acoustic energy delivery system withy a second driver element (15) (fig. 3),

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a second lens (19) (fig. 3) wherein a multiplexing circuit (41) can direct RF energy from an energy source to any combination of driver elements, and thus will alternately switch group of ejectors on and off (column 3, lines 47-49). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Hauser with a second lens and driver elements attached to a multiplexing circuit as taught by Sweet in order to provide the advantage of delivering a more specific amount of pharmaceutical during any span of time.

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- 30. Claims 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser (5,485,828) in view of Elrod ("Nozzless droplet...").
- 31. Regarding claims 21, 24 and 25, Hauser does not disclose the formation of capillary waves by relaxation of a principle mound. Elrod et al. teaches the formation of capillary waves from a principal mound (p. 3441, introduction, toward end of second paragraph) and the aerosol formed by the resulting capillary waves (p. 3444, Pulse Width: Ejection Stability and Droplet Diameter, first paragraph). Therefore it would have been obvious to one of ordinary skill at the time the invention was made to provide the invention of Hauser with the description of the formation of capillary waves as taught by Elrod et al. in order to provide the advantage of optimizing pharmaceutical output.
- 32. Claims 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser (5,485,828) in view of Blau (5372126)
- 33. Regarding claim 12, Hauser discloses sterilization (column 4, lines 1-2) but does not discloses an ejector head being sterilized by an ultraviolet radiation source. Blau discloses a sterilization mechanism that outputs ultraviolet energy for sterilization

purposes (column 1, lines 48-50). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Hauser with a sterilization mechanism as taught by Blau in order to provide the advantage of providing a safer means for providing pharmaceutical to a patient.

- 34. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser (5,485,828) in view of Ivri (6,205,999).
- 35. Regarding claim 17, Hauser discloses the claimed invention except for a circuit that detects air flow into a patient's lungs. Ivri teaches a flow sensor (24) (fig. 2) for detecting flow into a patient (column 7, lines 51-53) that couples to a transducer (26) to a circuit (column 7, lines 53-56). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the apparatus of Hauser with a sensor as taught by Ivri in order to provide the advantage of preventing accidental dosing of pharmaceutical product.

Response to Arguments

36. Applicant's arguments with respect to claims 1-7, 9-17, 19 and 21-26 have been considered but are moot in view of the new ground(s) of rejection. Further applicant's arguments in response to the drawing objections are no persuasive as it is not clear from the specification: where the fresnel lens is located, where the multiplexing circuit is located, and how the ultraviolet radiation source is part of the apparatus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is

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(571)270-7138. The examiner can normally be reached on Monday thru Friday,

9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/

Examiner, Art Unit 3771

/Steven O. Douglas/

Primary Examiner, Art Unit 3771